

Claim 18 has been amended to make clear that the method is directed to a film that adheres to and dissolves in the consumer's mouth. In addition, the claim has also been amended to recite that the oil mixture comprises at least two of the recited essential oils. The amendments are fully supported by the specification and claims as originally filed. Therefore, these changes are not new matter.

Claims 18 to 30 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for the reasons set forth on page 2 of the Official Action. Applicants respectfully traverse that rejection.

Applicants submit that one of ordinary skill in the art would understand the term "water-soluble ingredients" in light of the specification, and, thus, the claims are not indefinite. In particular, the present specification discloses a number of water-soluble ingredients that are useful in the presently claimed invention. In addition to the copper gluconate and sweeteners noted in the Office Action, useful water-soluble ingredients disclosed in the specification include, but are not limited to, sulfur precipitating agents, page 10, line 18, to page 11, line 4, saliva stimulating agents, page 11, lines 5 to 12, plasticizing agents, page 11, lines 13 to 14, surfactants, page 11, line 20, to page 12, line 3, stabilizing agents, page 12, lines 4 to 7, emulsifying agents, page 12, lines 8 to 11, and coloring agents, page 16, lines 6 to 19. Clearly, one of ordinary skill in the art would understand that the water-soluble ingredients that are dissolved in water to provide an aqueous solution may be selected from those ingredients listed in the specification, as well as other water-soluble ingredients. Moreover, the determination of which ingredients are water soluble could readily be made without undue experimentation.

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Therefore, the claims particularly point out and distinctly claim the subject matter applicants regard as the invention, and, thus, the claims are not indefinite. Accordingly, it is respectfully requested that the Examiner withdraw the rejection of Claims 18 to 30 under 35 U.S.C. § 112, second paragraph.

Claims 18 to 21, 24, 28, and 29 were rejected under 35 U.S.C. § 102 (b) as being allegedly anticipated by U.S. Patent No. 5,456,745 to Roreger et al. ("Roreger") for the reasons set forth on page 3 of the Office Action. In addition, claims 18 to 29 were rejected under 35 U.S.C. § 103 (a) as being allegedly unpatentable over Roreger for the reasons set forth on page 4 of the Office Action. Applicants respectfully traverse these rejections.

Prior to discussing the merit of the rejections, Applicants believe it would be helpful to describe the advantages of the present invention. The presently claimed invention is directed to method for preparing a physiologically compatible film that adheres to and dissolves in a consumer's mouth. The claimed method comprises mixing at least one water soluble film former and at least one stabilizing agent to provide a film-forming mixture, and dissolving water-soluble ingredients in water to provide an aqueous solution. The film forming mixture and the aqueous solution are then combined to provide a hydrated polymer gel. Oils are mixed to form an oil mixture that comprises at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, and menthol, and the oil mixture is added to the hydrated polymer gel. The result of the addition is then mixed to provide a uniform gel, which is cast on a substrate. The cast gel is dried to provide the film that adheres to and dissolves in a consumer's mouth. The resulting film provides unexpected and advantageous antimicrobial effect even with the use of relatively low level of essential

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oils. It is respectfully submitted that the cited art does not disclose or suggest a method for preparing a film that adheres to and dissolves in a consumer's mouth in which oils are mixed to form an oil mixture that comprises at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, and menthol.

In contrast to the presently claimed invention, Roreger discloses a flexible, hydrophilic, water swellable, but insoluble gel film, Column 1, lines 5 and 6, and the abstract. The disclosed gel film may be used as wound dressings, coverings for various medicals and substrates, as active substance carriers for the oral, buccal, rectal, vaginal, dermal, or transdermal application of active substances, for implants, and for artificial vessels. Column, 1, lines 10 to 16. The disclosed gel also has a high water absorption capacity. Column 2, lines 11 to 15. As all of the gels disclosed by Roreger are clearly insoluble, Roreger does not disclose or even suggest the presently claimed method for preparing a physiologically compatible film that adheres to and dissolves in a consumer's mouth, i.e., a soluble film. Therefore, it is respectfully submitted that the present claims are not anticipated by or obvious over Roreger.

Claims 18, 24, 28, and 29 were rejected under 35 U.S.C. § 102 (b) as being allegedly anticipated by U.S. Patent No. 5,629,003 to Horstmann et al. ("Horstmann") for the reasons set forth on page 3 of the Office Action. Also, claims 18 and 20 to 29 were rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Horstmann for the reasons set forth on page 5 of the Office Action. Applicants respectfully traverse these rejections.

Horstmann discloses a sheet-like, individually dosed presentation, which is in the form of a film, that rapidly dis

a mass consisting of 20 to 60 % by weight of at least one film-forming agent, 2 to 40 % of at least one gel forming agent, 0.1 to 35 % of at least one active substance, and up to 40 % of at least one inert filling agent. Column 3, lines 20 to 29, and the abstract. Processing of the presentation may be conducted according to a process known in the art. Column 4, lines 19 to 52.

Horstmann does not disclose or suggest a film comprising a mixture containing at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, let alone a method for preparing such a film. The only oil disclosed by Horstmann is peppermint oil. Therefore, Horstmann does not anticipate or render obvious the method of the presently claimed invention.

Claims 18, 19, 24, 28, and 29 were rejected under 35 U.S.C. §102(e) as allegedly being anticipated by U.S. Patent No. 5,948,430 to Zerbe et al. ("Zerbe") for the reasons set forth on page 3 of the Official Action. In addition, claims 18 to 29 were rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Zerbe for the reasons set forth on pages 5 and 6 of the Official Action. Applicants respectfully traverse these rejections.

Zerbe discloses a rapidly dissolving film that can be adhered to the oral cavity to release a pharmaceutically or cosmetically active agent, where the film comprises water-soluble polymers, one or more polyalcohols, one or more pharmaceutically or cosmetically active ingredients, and, optionally, one or more of plasticizers, surfactants, colorants, sweetening agents, flavors, flavor enhancers, and excipients, Column 2, lines 14 to 23. Zerbe discloses menthol as a cosmetically active agent for

comprises at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, and menthol, let alone a method of producing such a film. Therefore, Zerbe does not anticipate or render obvious the presently claimed invention.

Claims 30 was rejected under 35 U.S.C. § 103 (a) as allegedly being unpatentable over Roreger in view of U.S. Patent No. 4,562,020 to Hijiya et al. ("Hijiya") for the reasons set forth on page 6 of the Official Action, as allegedly being obvious over Horstmann in view of Hijiya for the reasons set forth on pages 6 and 7 of the Office Action, and as allegedly being obvious over Zerbe in view of Hijiya for the reasons set forth on page 7 of the Office Action. Applicants respectfully traverse these rejections.

As noted above, Applicants submit that Roreger, Horstmann, and Zerbe do not disclose or suggest the presently claimed method. With regard to Roreger, that reference discloses a method for making an insoluble gel film. Therefore, Roreger does not disclose or even suggest the presently claimed method of forming a film that dissolves in a consumer's mouth. Moreover, since Roreger teaches a method of preparing an insoluble film, it is respectfully submitted that the combination of the disclosure of Roreger with that of any of the other references is improper, as the other cited references disclose the preparation of soluble films.

With regard to Horstmann, that reference discloses a film that rapidly disintegrates in water, but does not disclose or suggest a method of making such a film that comprises the step of mixing oils to form an oil mixture that comprises at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, and menthol. Similarly, Zerbe discloses a rapidly dissolving film, but also fails to disclose forming a mixture of oils containing at least two of thymol, methyl

salicylate, eucalyptol, and menthol. Therefore, Horstmann and Zerbe fail to disclose or suggest the presently claimed method.

Hijiya does nothing to overcome the deficiencies of Roreger, Horstmann, and Zerbe. Hijiya discloses a continuous process for producing a self-supporting, water-soluble, glucan film. Column 2, lines 15 to 23, column 3, lines 60 to 65, and the abstract. Therefore, as discussed above, as Hijiya discloses preparation of a water-soluble film and Roreger discloses preparation of insoluble films, the combination of the cited references is improper, and the references provide no motivation to combine their teachings.

Moreover, in the examples, Hijiya discloses menthol as a cosmetically active agent. Hijiya does not disclose or even suggest a method comprising mixing oils to form an oil mixture that comprises at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, and menthol. Therefore, even if the disclosure of Hijiya is combined with that of Horstmann or Zerbe, the resulting combinations would not provide the presently claimed invention.


Therefore, as the combination of the disclosure of Roreger with that of the other references is improper, and Horstmann, Zerbe, and Hijiya, whether taken alone or in combination, do not disclose or suggest the presently claimed method, it is respectfully submitted that the present claims are not obvious over those references.

Wherefore, Applicants respectfully submit that the cited art, whether taken alone or together, does not disclose the presently claimed invention. Accordingly, it is respectfully requested that the claims be allowed and the case passed to issue.

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Applicants' undersigned attorney may be reached by telephone at (973) 385-4263. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

  
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## VERSION MARKED TO SHOW CLAIM CHANGES

18. (amended) A method for preparing a physiologically compatible film that adheres to and dissolves in a consumer's mouth said method comprising:
- mixing at least one water soluble film former and at least one stabilizing agent to provide a film-forming mixture;
  - dissolving water-soluble ingredients in water to provide an aqueous solution;
  - combining said film forming mixture and said aqueous solution to provide a hydrated polymer gel;
  - mixing oils to form an oil mixture that comprises at least two essential oils selected from the group consisting of thymol, methyl salicylate, eucalyptol, and menthol;
  - adding said oil mixture to said hydrated polymer gel and mixing to provide a uniform gel;
  - casting the uniform gel on a substrate; and
  - drying the cast gel to provide said film that adheres to and dissolves in a consumer's mouth.

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